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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,523

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Alan I. Green

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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

04/15/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,523	<b>Applicant(s)</b> GREEN ET AL.	
	<b>Examiner</b> SAMIRA JEAN-LOUIS	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/15/05, 04/17/08, 11/04/08, 11/24/08</u> .                  | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 1-22 are currently pending in the application.

Applicant's election of Group IV (i.e. cocktail composition encompassing claims 13-17 and newly added claims 20-22) and election of quetiapine as the D2 receptor blocker and idazoxan as the  $\alpha 2$  receptor antagonist in the reply filed on 01/30/09 is acknowledged. Examiner further acknowledged that claim 18 being drawn to a method was erroneously added to the composition and is hereby withdrawn from group IV. Moreover, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 1-12 and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Claims 13-17 and 20-22 are examined on the merits herein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "in which the second component" in line 1 of claim 15. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 13-17 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Pickar et al. (U.S. 2004/0127489 A1).**

***Based upon the earlier effective U.S. filing date of the reference, the applied reference constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived***

***from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.***

It is respectfully pointed out that a recitation of the intended use of the claimed invention in a composition claim must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of treating patients suffering from substance abuse is not afforded patentable weight.

Pickar et al. teach compositions useful for antipsychotic therapies containing a pharmaceutically acceptable carrier, effective amounts of  $\alpha 2$  adrenergic receptor antagonists and D2 dopamine receptor antagonist (instant claim 13; see abstract, pg. 1, paragraph 0002, pg. 2, paragraph 0016, and pg. 11, claims 7-10). Pickar et al. also teach that conventional antipsychotics are characterized mainly by D2 dopamine receptor blockade (see pg. 1, paragraph 0005). Preferably, the  $\alpha 2$  adrenergic receptor antagonist utilized according to the invention is a selective antagonist and is preferably idazoxan (instant claims 15, 20, and 22; see pg. 4, paragraph 0037). As for the D2 dopamine receptor antagonist, Pickar et al. further teach that once the desired dose of

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the  $\alpha_2$  adrenergic antagonist has been reached, the preferred dose of the atypical antipsychotic should be roughly 50% of the normal recommended dose range and include administration of quetiapine at 150-450 mg/day (instant claims 14 and 21-22; see pg. 4, paragraphs 0038 and 0042). Additionally, Pickar et al. teach that the selection of atypical antipsychotic and  $\alpha_2$  antagonist combinations that satisfy these binding affinity ratios will result in enhanced therapeutic efficacy of atypical antipsychotics and may provide a similar relative balance of pharmacological effects to that of clozapine (instant claim 17; see pg. 5, paragraph 0050). Importantly, Pickar et al. teach the administration of quetiapine in combination with idazoxan led to an enhanced ratio score (see pg. 9, paragraphs 0105 and 0109).

As for the limitation that the cocktail is characterized by strong blockade of the  $\alpha_2C$  receptor, the Examiner asserts that the cocktail possess the same characteristic profile as the instant claimed invention given that these characteristics are inherent to the cocktail composition.

It is noted that In re Best, 195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Accordingly, the teachings of Pickar et al. anticipate claims 13-17 and 20-22.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L./

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617